UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/050,249	03/30/1998	HARUKI OKAMURA	OKAMURA=2B	6601

1444 7590 09/27/2007

BROWDY AND NEIMARK, P.L.L.C.
624 NINTH STREET, NW
SUITE 300
WASHINGTON, DC 20001-5303

EXAMINER	
JIANG, DONG	

ART UNIT	PAPER NUMBER
1646	

MAIL DATE	DELIVERY MODE
09/27/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/050,249	OKAMURA ET AL.	
	Examiner	Art Unit	
	Dong Jiang	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 July 2007*.

2a)☒ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *93,95 and 98-120* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *93,95 and 98-120* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED OFFICE ACTION

Applicant's amendment filed on 23 July 2007 is acknowledged and entered. Following the amendment, claims 93 and 118 are amended.

Currently, claims 93, 95 and 98-120 are pending and under consideration.

Rejections under 35 U.S.C. 112:

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 93, 95 and 98-119 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The newly amended claim 93 recites "which recognizes IGIF or IL-18 *that has an activity* of ... *at a position* ...". It is unclear how the protein induces an activity at a position on a gel. Claim 118 is similarly indefinite.

The remaining claims are included in this rejection because it is dependent from the specifically mentioned claims without resolving the indefiniteness issue belonging thereto.

Rejections Over Prior Art:

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. 1.56 to point out

the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claims 93, 95 and 98-120 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Nakamura *et al.* (*Infect. Immun.* 61: 64-70, 1993), for the reasons set forth in the previous Office Actions.

Applicants argument filed on 23 July 2007 has been fully considered, but is not deemed persuasive for reasons below.

At pages 11-12 of the response, applicants cite the Nakamura reference (*Infect. Immun.* 1995, 63: 3966-3972) that "[T]hus IGIF in the serum sample was proved to be the same IGIF as that found in liver extract, and it was considered to be bound to another protein or to exist in an oligomeric form", and applicants argue that this statement means that it is not Nakamura but Okamura who first succeeded in purifying and isolating IGIF (molecular weight of 19 kDa on SDS-PAGE), which had been neither purified nor isolated by Nakamura. Applicants further argue that the Nakamura reference states "a *novel* costimulatory factor" for the IGIF, which should make it clear that Okamura recognized that he succeeded in newly purifying and isolating IGIF (molecular weight of 19 kDa on SDS-PAGE), and that if Okamura did not believe that he had found a new substance, then Okamura would not have submitted his paper at the "American Society for Microbiology". This argument is not persuasive because Nakamura also purified the same IGIF, which is evidenced by the statement "it was further purified to apparent homogeneity by PAGE" (abstract), and by the detailed purification procedures (page 65, the last paragraph to the last paragraph of page 66). Therefore, Okamura is not the first to purify and isolate the IGIF. Although Nakamura's factor did not appear as 19 kDa band on SDS-PAGE, it is the same factor as that of Okamura, as evidenced by Okamura's statement pointed out by applicants (see above). Further, Nakamura's factor possesses the same biological activity as that of Okamura. Therefore, *even if* Nakamura's factor were less pure, it is irrelevant because high purity is not required for generating antibodies such as that of the present invention. With respect to the argument as to what Okamura believed and where the publication was submitted, it is irrelevant

to the determination of novelty of an invention because it is determined by fact and evidence, not someone's belief or the name/reputation of a journal.

Applicants further argue, on page 12 of the response, that Okamura's statement cited by the examiner should be considered to be his speculation about reasons why Okamura's IGIF is different from Nakamura's factor in MW (bound to another protein, or existed in an oligomeric form), that Okamura never states that his IGIF is the same substance as Nakamura's factor. This argument is not persuasive because, while the examiner agrees that Okamura's explanation on the difference in MW between his IGIF and Nakamura's factor is considered speculation, it is irrelevant because Okamura clearly states "[T]hus IGIF in the serum sample was *proved* to be the same IGIF as that found in liver extract".

At pages 12-13 of the response, applicants argue that in connection with this prior art issue, the differences between IGIF and Nakamura's factor is shown in an attached schematic diagram. This argument is not persuasive for the reasons of record and the same reasons above because the schematic diagram adds nothing new to applicants argument, and it shows nothing more than the difference in MW, which issue has been addressed thoroughly in the previous Office Actions and above.

At page 13 of the response, Applicants further argue, citing the literature of monoclonal antibody for IL-10 in "The Cytokine Handbook", that this implies that the molecular species of 19 kDa derived from Nakamura's factor may be different from the IGIF or IL-18 of the claimed invention in its antigenicity, and that thus, the molecular species of 19 kDa (55 kDa?) derived from Nakamura's factor may not have been effective to obtain a monoclonal antibody which recognizes IGIF or IL-18. This argument is not persuasive because the IL-10 case does not represent a generalized phenomenon in the art, and there is no scientific basis or evidence to support such argument. Applicants further argue that both Nakamura and Okamura do not recite that they actually obtained monoclonal antibodies, which recognize IGIF even though they did indicate the necessity of such monoclonal antibodies. This argument is not persuasive because the rejection is not anticipating, but obviousness rejection. The person of ordinary skill in the art would have been motivated to make the antibodies to Nakamura's factor, and reasonably would have expected success because Nakamura indeed indicated the necessity of such monoclonal

antibodies, and because of the fact that the technology of making antibodies was well established, and widely used in the art at the time the present invention was filed.

Conclusion:

No claim is allowable.

Advisory Information:

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication should be directed to Dong Jiang whose telephone number is 571-272-0872. The examiner can normally be reached on Monday - Friday from 9:30 AM to 7:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol, can be reached on 571-272-0835. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Lorraine Spector

LORRAINE SPECTOR
PRIMARY EXAMINER

Dong Jiang, Ph.D.
Patent Examiner
AU1646
9/20/07